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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,522	03/10/2005	Shinichiro Yokoyama	MOR-254-A	5175

48980 7590 08/28/2009  
YOUNG BASILE  
3001 WEST BIG BEAVER ROAD  
SUITE 624  
TROY, MI 48084

EXAMINER
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MEDWAY, SCOTT J

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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08/28/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@youngbasile.com  
audit@youngbasile.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,522	<b>Applicant(s)</b> YOKOYAMA ET AL.	
	<b>Examiner</b> SCOTT MEDWAY	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/30/2009 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase “wherein when in the targeted position, the guide wire is partially removed from the guide lumen to a position distal the bypass holes to work with the stroke means to allow for the bypass lumen.” is unclear because the claim does not add any limitations after the words “bypass lumen” and it is not known what limitations, if any, are intended to follow the words “bypass lumen”. Hence, it is not easily discernible the limitations intended to be encompassed by the claim.

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Claims 2 and 4 are rejected by being dependent on claim 1.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (U.S. Pat. 5,135,484) in view of Ohara et al (U.S. Pat. 4,360,324, hereinafter "Ohara").**

Regarding claim 1, Wright discloses a device for infusion therapy, comprising as in Fig. 3 a balloon catheter; a guide wire (56) to be inserted into a guide lumen (50) that guides the catheter body to a target position; a plurality of lumens (e.g. 60, 72) extending along an axis; heart pulsation detection means (col. 3, lines 22-25); and two expandable balloons (48) arranged in series. The plurality of lumens comprise an infusion lumen (60), which can supply a drug-like slurry to the outside of the catheter, is shown in Fig. 3 to have an infusion hole located in between the two balloons. The device comprises: balloon lumens (44) communicating with the insides of the two balloons to control expansion of the balloons; a bypass lumen (72) which is located outside of the two balloons, which contains bypass holes (e.g., 70 and the exit from lumen 72 being a hole) which allows flow (col. 4, lines 44-46); and a lumen (e.g. 56, 72) which serves as a guide lumen to communicate with the outside of the catheter body and a bypass lumen (col. 4, lines 41-50). The guide lumen (72) and bypass lumen (72) are disclosed by Wright to be the same lumen in at least one embodiment.

It is noted that Wright does not disclose stroke means for causing the guide wire to stroke in synchronization of the pulsation of the heart. Ohara discloses a pulsatile pumping apparatus that has means which stroke in synchronization with the pulsation of the heart (col. 3, lines 517-65; col. 7, lines 11-20). Since Wright discloses the desire to permit a high level of fluid flow around a treatment zone via bypass lumen and to detect

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and monitor fluid flow and pressure in a vessel (col. 3, lines 22-25; col. 4, lines 54-56; col. 5, lines 25-27) and to use for instance a piston pump (col. 5, line 36) to pump material to and from the vessel site, it would have been obvious to one of ordinary skill in the art at the time of the invention to consider adapting the flow detection system present in the device of Wright for integrating the means to control stroke of a guide wire (for instance as a pump-like store-and-release mechanism as taught by Ohara, to ensure a high level of blood flow through the bypass lumen. Examiner asserts that at some point during the procedure disclosed by Ohara, a guide wire in combination with a pump could be partially removed from a guide lumen to a position distal the bypass holes, which would allow the stroke means of Wright to perform their intended function in the combination of Wright in view of Ohara.

It is additionally noted that Wright does not disclose the balloon catheter being previously combined with the guide wire and inserted. Since it has been held that separating into two devices a process which can alternately be performed as integral involves only routine skill in the art, one of ordinary skill in the art at the time of the invention could be motivated to combine or separate the guide wire and balloon previous to insertion as a matter of choice.

Regarding claim 2, Wright discloses the device to have a lumen (44) which inflates both of the balloons shown in Fig. 3 (col. 3, lines 1-2).

**8. Claim 4 is rejected as being unpatentable over Wright (U.S. Pat. 5,135,484) in view of Ohara et al (U.S. Pat. 4,360,324), further in view of Corday et al (U.S.**

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**Pat. 4,689,041, hereinafter “Corday”) or Hall et al (U.S. Pat. 6,196,230 B1, hereinafter “Hall”) or Smits (U.S. Pat. 6,549,812 B1).**

It is noted that Wright discloses the use of the device in the coronary artery, it does not disclose the device for insertion into a coronary vein. The patents of Corday, Hall and Smits disclose the use of balloon catheter systems for introduction of drugs or for occlusion or removal of material from a vessel where the devices are used for insertion into a coronary vein. Accordingly, one of ordinary skill in the art at the time of the invention would be prompted to modify the combination of Wright in view of Ohara so that it can be used in the coronary vein, which is a function considered obvious in view of the conventionality of this particular intended use (e.g., for infusing material into a vessel).

### ***Response to Arguments***

9. Applicant's arguments filed 07/13/2009 have been fully considered but they are not persuasive.

In response to Applicant's argument that Wright does not teach or suggests the use of a lumen for each balloon, Examiner asserts that such a limitation is not positively recited in claim 1. Claim 1 merely recites “balloon lumens that communicate within sides of said two balloons to control expansion of said balloons”. Wright discloses that limitation as described above.

### ***Conclusion***

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10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant is directed to the *Notice of References Cited*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/  
Examiner, AU 3763  
08/24/2009

/Nicholas D Lucchesi/



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Supervisory Patent Examiner, Art Unit 3763